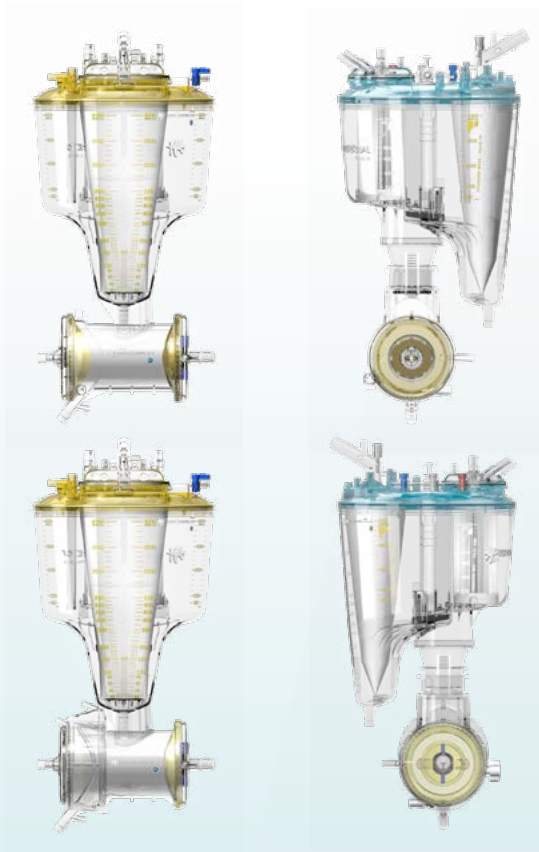


# INSPIRE® 6 PH.I.S.I.O.



Optimized perfusion

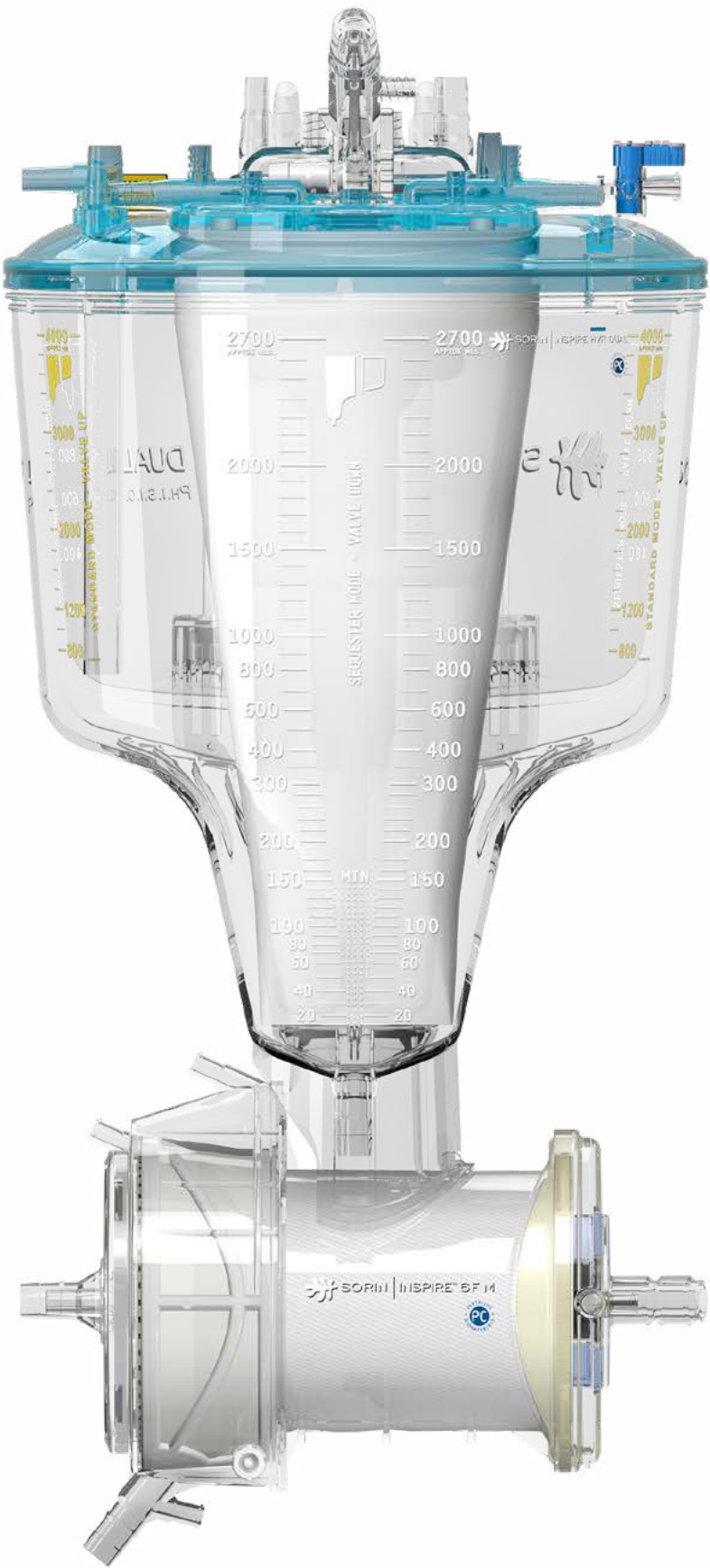
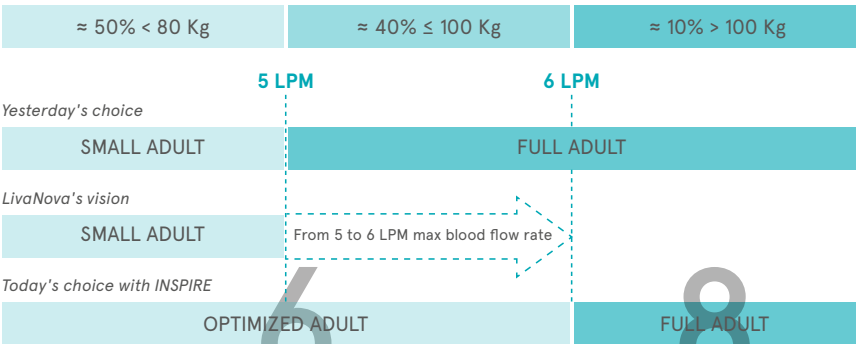
# Optimized perfusion

The goal of optimized perfusion is to minimize the impact of Cardiopulmonary Bypass (CPB) on patient outcomes by focusing on reducing hemodilution and blood contact surface area, minimizing gaseous micro emboli (GME) and improving biocompatibility, while providing high performance. Until Inspire, small adult devices have been considered the benchmark for optimized perfusion, but are limited in flow to 5 LPM. By extending the maximum blood flow rate from 5 to 6 LPM, the new INSPIRE 6 LPM optimized adult oxygenator systems extend the benefits of small adult devices to a wider patient population.

“ The INSPIRE 6 is a safe and efficient low prime oxygenator with an optimal gas transfer rate. The oxygenator is suitable for minimized extracorporeal systems and may contribute to a better patient outcome.\* ”

## ADULT PATIENT POPULATION AND OXYGENATOR OF CHOICE

Patient Body Weight & Distribution per INSPIRE Market Assessment Study (MAS) database



## THE ONLY OPTIMIZED ADULT OXYGENATOR SYSTEMS

INSPIRE 6 LPM oxygenator systems are the only optimized adult oxygenator systems with a low blood contact surface area which can minimize impact on hemodilution and effectively control GME, while offering full performance up to 6 LPM maximum blood flow, therefore covering a wide patient flow requirements.

INSPIRE 6 LPM oxygenator systems offer the ideal solution for optimized perfusion and have been conceived to help clinicians minimize the impact of CPB on a wide patient population, aiming to improve outcome and reduce cost of care.

They are available with and without integrated arterial filter, with traditional single chamber reservoir or unique DUAL chamber reservoir.

INSPIRE® 6  
PH.I.S.I.O.

INSPIRE® 6F  
PH.I.S.I.O.

INSPIRE® 6 DUAL  
PH.I.S.I.O.

INSPIRE® 6F DUAL  
PH.I.S.I.O.

- Full performance up to 6 LPM
- Minimized impact on hemodilution
- Superior GME handling\*
- Dual chamber reservoir for enhanced biocompatibility (INSPIRE 6 DUAL and 6F DUAL)

\* vs. competitive design

“ Modern cardiac surgery aims at reducing operative trauma to patients by applying more and more minimally invasive surgical techniques. However, only part of the operative trauma in cardiac surgery is related to surgical technique. Part of the operative trauma is caused by the extracorporeal circulation. Therefore, it is of utmost importance not only to optimize surgical technique, but also to optimize the perfusion system of extracorporeal circuits and the management of cardiopulmonary bypass. The goals of ECC optimization are a reduction of hemodilution by reducing the priming volume, a reduction of the foreign surface area, an improvement of microbubble handling and optimized suction blood management. ”

\*Thomas Dreizler, S. Paal, M. Klein, V. Falk, C.T. Starck  
Clinic of Cardiac and Vascular Surgery, University Hospital Zurich, Zurich, Switzerland  
Presented at 15<sup>th</sup> European Congress on Extracorporeal Circulation Technology, Toledo June 12<sup>th</sup>-15<sup>th</sup> 2013

Perfusion. 2013 Jul;28(4):292-7. doi: 10.1177/0267659113476126. Epub 2013 Feb 12. Initial results of an optimized perfusion system. Starck C, Bettex D, Felix C, Reser D, Dreizler T, Hasenclever P, Falk V. Source: Clinic of Cardiac and Vascular Surgery, University Hospital Zurich, Zurich, Switzerland.



FULL PERFORMANCE UP TO 6 LPM

THE ONLY OXYGENATOR WITH 6 LPM MAXIMUM RATED BLOOD FLOW

- The INSPIRE 6 LPM oxygenators can offer the benefits of less hemodilution and low blood contact surface area found in small adult oxygenators, but go beyond their 5 LPM rating.
- The remarkably efficient INSPIRE oxygenator longitudinal flow design maximizes blood exposure allowing full gas exchange performance up to 6 LPM.
- The newly designed polyurethane heat exchanger is capable of highly efficient heat transfer up to 6 LPM.



OUTSTANDING LOW PRIME VOLUME AND BLOOD CONTACT SURFACE AREA

- Only 1,4 m² membrane surface area and 0,4 m² for the heat exchanger.
- More than 30% reduction in foreign surfaced area vs. full adult 2.5 m² competitive devices.
- Only 184 ml oxygenator priming volume for the standard version.
- Only 284 ml oxygenator priming volume for the version with integrated arterial filter.

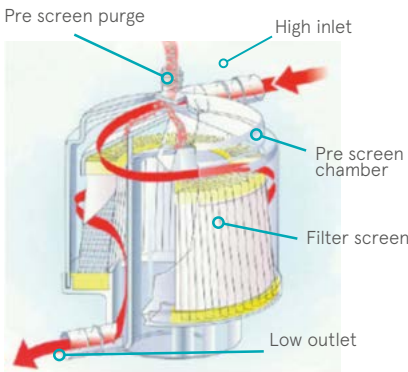
More than 30% reduction in foreign surface area exposure



INTEGRATED ARTERIAL FILTER WITH SUPERIOR GME HANDLING\*

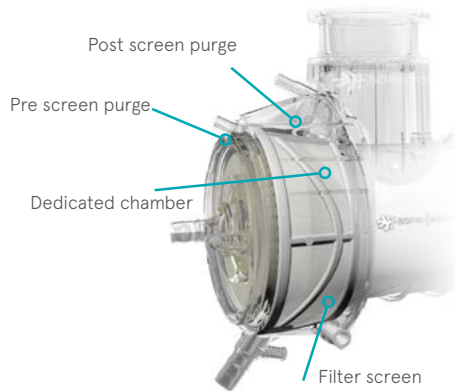
From its conception, the arterial filter has given confidence to the perfusionists by providing additional protection for the patient, hence adoption rate in recent years has consistently increased. Integration of arterial filter and oxygenator improves safety by reducing connections, reduces hemodilution and makes setup easier. **The INSPIRE integrated arterial filter design, thanks to its dedicated compartment, offers superior GME handling compared to competitive designs, while ensuring minimized impact on hemodilution.**

Common Filter Elements:



The INSPIRE Integrated Arterial Filter was designed for safety and ease of use, integrating the essential features of separate arterial filters. Studies have shown arterial filters with a pre-screen chamber and purge capability provide better protection from air and GME<sup>1</sup>, by allowing a reduction of blood velocity before the screen. To facilitate air removal, INSPIRE includes purge ports on both sides of the 38 µ screen. This unique design allows for the first time to have full visibility on the filter outer side.

Inspire Integrated Arterial Filter:



<sup>1</sup> Evaluation of Integrated and Non-Integrated Oxygenator/Arterial Filters for Gaseous Microemboli Removal  
Larry Petree, MS; Bob Eke, BA; Rob Haynes, BA; Cheri Voorhees, BAH(ASCP)SH  
Sorin Group, Arvada, Colorado, USA

\* vs. competitive design

MINIMIZED IMPACT ON HEMODILUTION

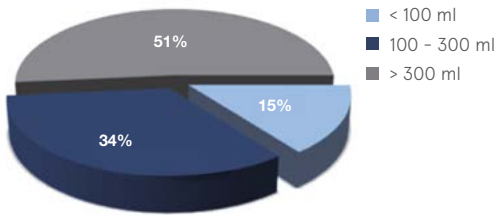
Minimizing hemodilution contributes to decreased blood transfusions and improved clinical outcomes during and after cardiopulmonary bypass (CPB). Until now, the impact on hemodilution was associated with oxygenator module static priming volume.

With INSPIRE we are introducing a new concept: the oxygenator system dynamic operating volume (DOV), which allows to evaluate the overall hemodilution impact of an oxygenator system.

The oxygenator system DOV is defined as the sum of four elements: the oxygenator module priming volume, the reservoir minimum operating level, the venous filter dynamic hold-up volume and the venous collector priming volume.

INSPIRE oxygenator systems minimize the impact on hemodilution at a system level by featuring low priming oxygenator modules, the lowest minimum operating level in the reservoir (150 ml), outstanding low venous filter dynamic hold-up volume and low venous collector priming volume. During the Market Assessment Study, about 80% of clinicians reported they could achieve a priming volume reduction over 100 ml, while over 50% reported a decrease of 300 ml or more.

Overall priming volume reduction



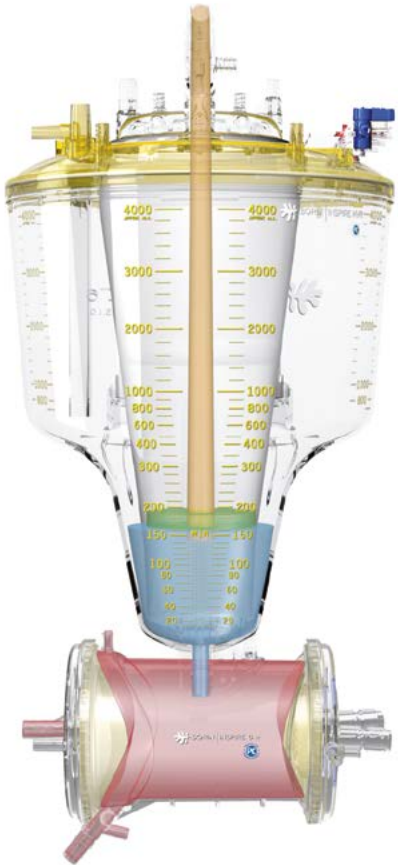
DYNAMIC OPERATING VOLUME (DOV)

Venous collector priming volume

Venous filter hold-up volume

Minimum operating level

Oxy module priming volume



From Oxygenator Module to Oxygenator System

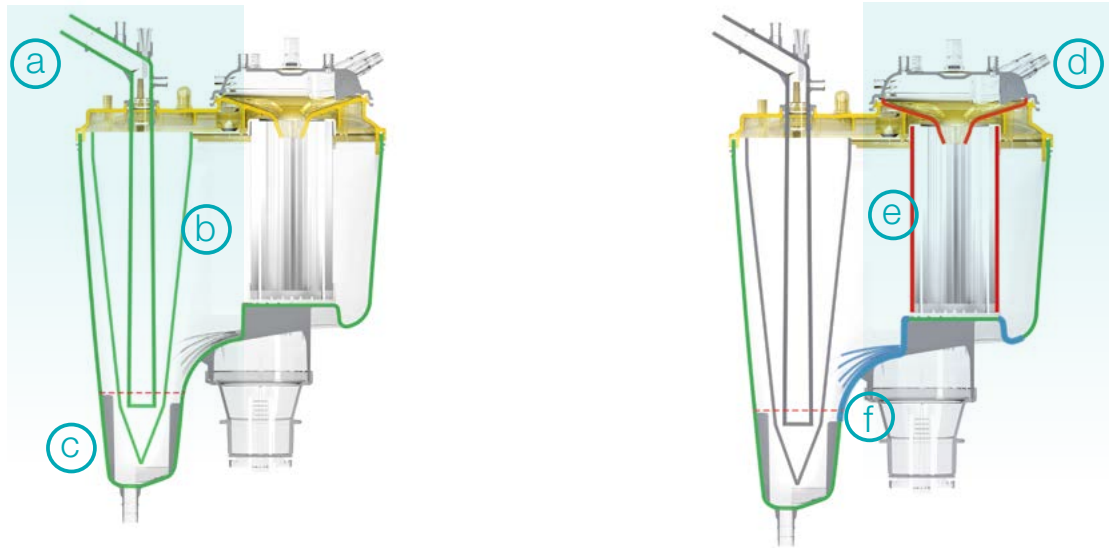


## SUPERIOR GME HANDLING\*

Gaseous microemboli are commonly indicated as potential sources of neurological damage after CPB. Dedicated design solutions within the INSPIRE HVR, HVR DUAL and in the INSPIRE oxygenator modules provide effective gaseous microemboli (GME) control, by approaching GME handling at a system level.

### DESIGNED FOR EFFECTIVE AIR MANAGEMENT

It has been widely demonstrated by recent studies\*\* that the reservoir plays a key role in controlling GME: *"The venous reservoir significantly influences embolic load delivered to the oxygenator (  $p < .001$ ). [...] Venous reservoir design influenced the overall GME handling ability"*. INSPIRE HVR and HVR DUAL have been designed both on venous and cardiotomy side to maximize GME control through a mix of fluid-dynamics and filtration capabilities.



### HVR VENOUS SIDE

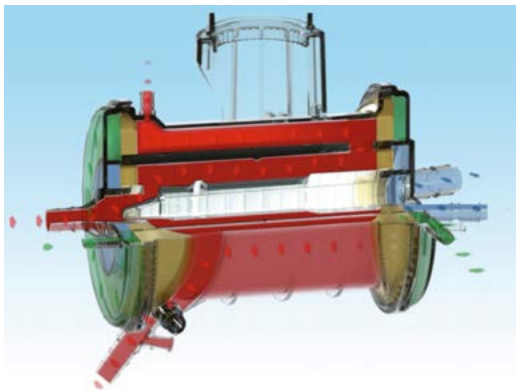
- a. Conical venous return tube to slow down blood speed and always submerged to avoids splashing
- b. Dual filter screen on venous section ( $41\mu + 120\mu$ )
- c. Internal frame with specific design to slide air bubbles towards the top

### HVR CARDIOTOMY SIDE

- d. Suction blood is accompanied toward the filter floor or to the polyurethane sponge to minimize splashing
- e. Pleated  $41\mu$  screen filter (vs. depth) designed for low GME and superior debris management
- f. Diverging ribs on cardiotomy floor gently accompany blood to reduce blood speed

### OXYGENATOR MODULE DESIGN

For GME, the longer path oxygenator design provides more blood side pressure and opportunity to remove air across the membrane fibers.



\* vs. competitive design

\*\* J Extra Corpor Technol. 2011 Sep;43(3):107-14.

In vitro evaluation of gaseous microemboli handling of cardiopulmonary bypass circuits with and without integrated arterial line filters. Liu S, Newland RF, Tully PJ, Tuble SC, Baker RA.

## DUAL CHAMBER RESERVOIR FOR ENHANCED BIOCOMPATIBILITY

INSPIRE DUAL systems provide clinicians new options for activated suction management allowing a dedicated solution for advanced perfusion. The combination of INSPIRE DUAL systems, PHISIO PC coating and LivaNova XTRA autotransfusion system, offers clinicians a **comprehensive solution to enhanced biocompatibility**.

### ACTIVATED SUCTION SEPARATION

*"Aspirated blood contaminated by tissue contact is the most important activator of the coagulation system and the principal cause of hemolysis during cardiopulmonary bypass."*\*

Retainment of blood aspirated out of nonvascular structures will significantly reduce morbidity of CPB. Blood activated by means of tissue factor should be discarded or processed with a cell salvage system. INSPIRE DUAL Reservoir unique design offers new options for activated suction management combined with maximum flexibility.



### EASY PROCESSING AND FULL REVERSIBILITY

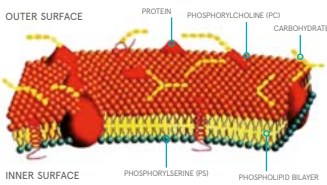
Separation of activated suction blood and washing with XTRA autotransfusion system is made extremely easy by the chamber sequestration valve mechanism. At the same time, clinicians have always at hand the choice to separate activated suction blood or the option to reverse INSPIRE DUAL to a single chamber venous reservoir.



### COATING

*"Combination of coating and avoidance of shed blood recirculation maintained physiological coagulation levels and markedly reduced red blood cell trauma in extracorporeal circulation procedures."*\*\*

Activated suction blood separation with INSPIRE DUAL oxygenator systems, combined with PHISIO PC coating, allows to make a further step towards enhanced biocompatibility.



### ACTIVATED SUCTION PROCESSING

*"Current evidence suggests that the use of a cell saver reduces exposure to allogeneic blood products or red blood cell transfusion for patients undergoing cardiac surgery."*\*\*\*

*"Cerebral microembolization during cardiopulmonary bypass may lead to cognitive decline after cardiac surgery. Transfusion of the unprocessed shed blood (major source of lipid microparticulates) into the patient during cardiopulmonary bypass is common practice to reduce blood loss and blood transfusion.[...] The present report demonstrates that processing of shed blood with cell saver results in clinically significant reduction in postoperative cognitive dysfunction after cardiac surgery."*\*\*\*\*

XTRA has a specific fat removal protocol to remove the fat emboli between 99-100%.



\*J Thorac Cardiovasc Surg. 2002 May;123(5):951-8. Tissue factor as the main activator of the coagulation system during cardiopulmonary bypass. De Somer F et al.

\*\* J Thorac Cardiovasc Surg. 2003 Nov;126(5):1504-12. Physiological coagulation can be maintained in extracorporeal circulation by means of shed blood separation and coating. Albes JM et al.

\*\*\* Anesth Analg. 2009 Aug;109(2):320-30. The efficacy of an intraoperative cell saver during cardiac surgery: a meta-analysis of randomized trials. Wang G, Bainbridge D, Martin J, Cheng D. Circulation. 2007 Oct 23;116(17):1888-95. Epub 2007 Oct 8.

\*\*\*\* Continuous-flow cell saver reduces cognitive decline in elderly patients after coronary bypass surgery. Djaiani G, \*\* Perfusion. 2012 Jul;27(4):278-83. doi:10.1177/0267659112442222. Epub 2012 Mar 29.



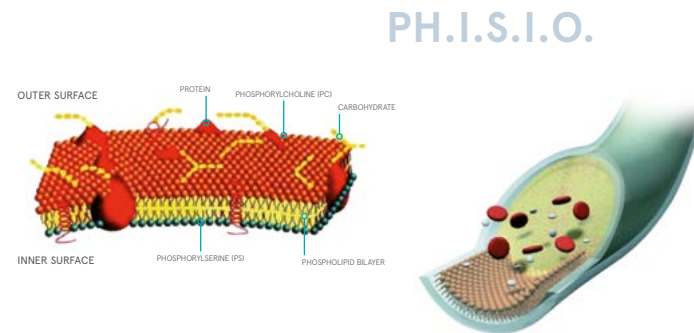
## PH.I.S.I.O. COATING

PH.I.S.I.O PC coating has proven to be extremely effective in reducing platelet activation and cell adhesion to foreign surface.

*"The interaction of blood with foreign artificial surfaces during cardiopulmonary bypass (CPB) has been recognized as a major stimulus in evoking a systemic inflammatory and metabolic response. **Phosphorylcholine (PC) is a new-generation coating material designed to ameliorate biocompatibility and thereby to reduce the detrimental interactions of CPB**".\**

PH.I.S.I.O PC coating is a physiological inert material mimicking the endothelium widely proven by clinical experience on more than two millions patients to date.

All INSPIRE oxygenators are PH.I.S.I.O PC coated and, PH.I.S.I.O PC coating is also applied to all INSPIRE HVR and HVR DUAL blood contact surfaces: HVR bucket and venous return collector, frame of venous return filter, both venous and cardiotomy filtering nets.



## SAFE, EASY AND FLEXIBLE

The INSPIRE oxygenator systems are flexible and versatile. **INSPIRE is the most vertically compact oxygenator system on the market today. It allows optimal handling during the case and minimal storage on the shelf.** A single, newly designed bracket fits the entire family for maximum convenience. Ergonomics, port orientation and system priming have been optimized to offer easy set-up and operational flexibility.

## FLEXIBILITY AND EASY HANDLING

- Most vertically compact design on market (< 500 mm)
  - Better venous drainage
  - Less storage volume
- 4.5 liter max. reservoir capacity volume
  - 4 liter maximum operating volume
  - Easy reading of graduated scales
- Maximal system rotational freedom
- Safe and easy set-up
  - Single sided sterile and unsterile ports on oxygenator module to avoid mis-connections
- Quick priming and easy de-bubbling
  - Fast priming with membrane fluid-dynamics designed to optimize air removal during priming



## ONE BRACKET FITS ALL FAMILY MODELS

- Quick priming and easy de-bubbling
- Robust and durable
- Easy to clean
- Available with "Fast Clamp" for C5/S5 HLM



\* J Card Surg. 2009 Jul-Aug;24(4):363-8. doi: 10.1111/j.1540-8191.2009.00895.x. Phosphorylcholine-coated circuits improve preservation of platelet count and reduce expression of proinflammatory cytokines in CABG: a prospective randomized trial. Schulze CJ, Han L, Ghorpade N, Etches WS, Stang L, Koshal A, Wang SH.

# LIVANOVA

## THE FIRST CARDIOPULMONARY BYPASS SYSTEM

LivaNova Heartlink is the first perfusion system to provide a unique link **between perfusion data, patient parameters and product information to assist with case management and Goal Directed Perfusion principles.** INSPIRE oxygenator family is the latest addition that, together with S5/C5 Heart-Lung machines, Connect Perfusion Charting System and XTRA auto-transfusion machine, completes the LivaNova Heartlink System. The LivaNova Heartlink card, available only with LivaNova INSPIRE, is the key to make system features available in Connect.



## HEARTLINK CARD:



### THE KEY TO CONTINUOUS PRACTICE IMPROVEMENT

HeartLink card, in conjunction with HeartLink reader and Connect, provides **automatic loading of data related to INSPIRE oxygenator systems and PTS** thus **reducing the number of manual operations** to collect this data and **potentially contributing to limit the number of human errors.** Connect is approved as a medical device and data transfer via HeartLink card has been validated to guarantee data integrity. Transferring data via the HeartLink card and including it in the database, together with patients' and procedures' data, allows clinicians to obtain a more complete perfusion record, **thus contributing to process standardization, a key to a continuous practice improvement.**

### THE KEY TO INVENTORY TRACKING

Inventory management serves as an important and powerful tool to improve many key aspects of healthcare, tracking details such as quantities, usage rates and expiration dates so that items remain in stock and are used before they expire.

Thanks to HeartLink card and System, INSPIRE oxygenators and all the other components part of the INSPIRE Perfusion Tubing Set can be tracked in the perfusion report and the related information retained in Connect **for future statistical analysis and inventory reporting.**

### THE KEY TO GOAL DIRECTED PERFUSION

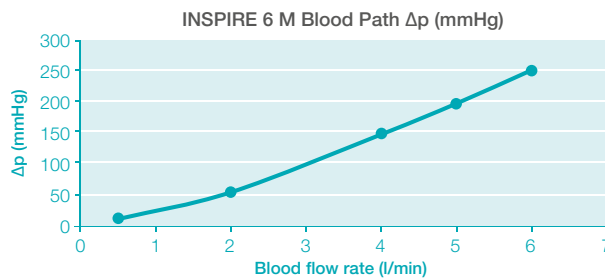
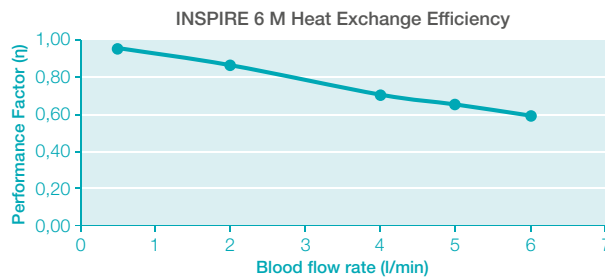
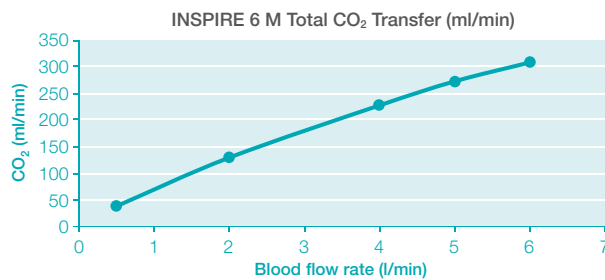
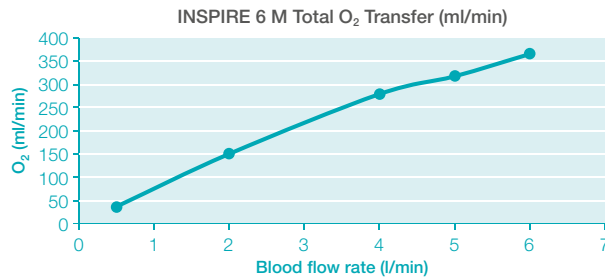
**HeartLink Card enables the GDP Monitor feature inside Connect** allowing implementation of Goal Directed Perfusion principles in the operating room to **help in adapting adequacy of perfusion to patients while contributing to shorten ICU & hospital length of stay.** With GDP Monitor it is possible to observe in real time and record parameters related to oxygen and carbon dioxide exchange and, in particular, **monitor DO<sub>2</sub> and DO<sub>2</sub>/VCO<sub>2</sub> to ensure they are above their critical value** as this has been associated with a reduction in acute kidney injury (AKI) occurrence and reduced lactate peak level during CPB.

## PERFORMANCE CHART

### INSPIRE® 6 DUAL PH.I.S.I.O.

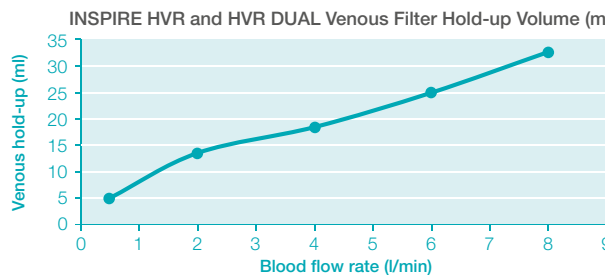
#### TEST CONDITIONS

(Bovine blood - Hb 12±0.2 gr/dl - B.E. 0±2mEq/l  
- Venous pCO<sub>2</sub> 45±5 mmHg - O<sub>2</sub> Venous Sat. 65±5%  
- Blood Temp. 37±1 °C - Q<sub>6</sub>/Q<sub>8</sub>=1 - FiO<sub>2</sub> 100% - Qw=11,5±0,2 l/min)



#### TEST CONDITIONS

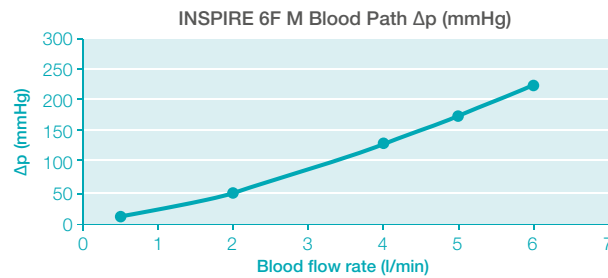
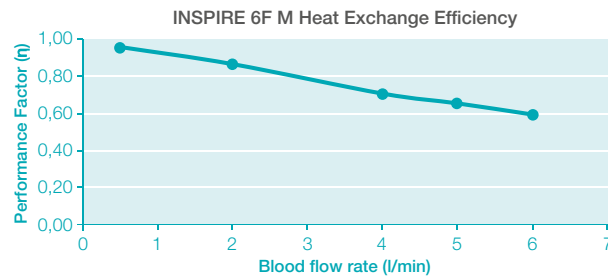
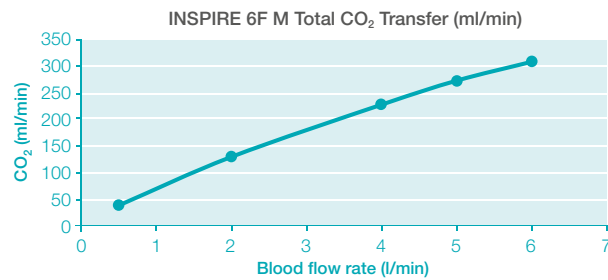
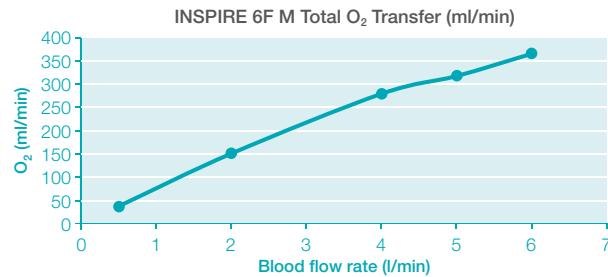
(Bovine blood - Hb 12±0.2 gr/dl - Blood Temp. 37±1 °C)



### INSPIRE® 6F DUAL PH.I.S.I.O.

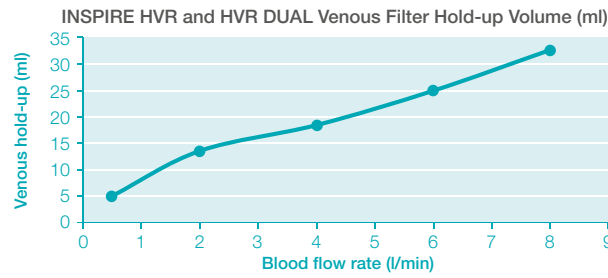
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- Blood Temp. 37±1 °C - Q<sub>6</sub>/Q<sub>8</sub>=1 - FiO<sub>2</sub> 100% - Qw=11,5±0,2 l/min)



#### TEST CONDITIONS

(Bovine blood - Hb 12±0.2 gr/dl - Blood Temp. 37±1 °C)



## TECHNICAL SPECIFICATIONS

### INSPIRE® 6 PH.I.S.I.O.

OXYGENATOR SYSTEM	
- Oxygenator system DOV @ max flow	402 ml
- Biocompatible coating	Phosphorylcoline (PHISIO)
RESERVOIR	
MAX. VOLUME CAPACITY (approx.)	4500 ml
MAX. OPERATING LEVEL (approx.)	4000 ml
MIN. OPERATING LEVEL	
150 ml	
FILTRATION SECTIONS	
Venous reservoir section	
- Filtering media	41 µm polyester outer screen + 120 µm inner polyester net
Cardiotomy reservoir section	
- Filtering media	41 µm polyester screen
OXYGENATOR MODULE	
MAXIMUM BLOOD FLOW RATE	6 l/min
STATIC PRIMING VOLUME (oxy module + heat exchanger average value)	184 ml
MEMBRANE SECTION	
- Surface area (approx. value)	1,4 m <sup>2</sup>
HEAT EXCHANGER SECTION	
- Material type	Polyurethane
- Surface area (approx. value)	0,4 m <sup>2</sup>

### INSPIRE® 6F PH.I.S.I.O.

OXYGENATOR SYSTEM	
- Oxygenator system DOV @ max flow	502 ml
- Biocompatible coating	Phosphorylcoline (PHISIO)
RESERVOIR	
MAX. VOLUME CAPACITY (approx.)	4500 ml
MAX. OPERATING LEVEL (approx.)	4000 ml
MIN. OPERATING LEVEL	
150 ml	
FILTRATION SECTIONS	
Venous reservoir section	
- Filtering media	41 µm Polyester outer screen + 120 µm inner Polyester net
Cardiotomy reservoir section	
- Filtering media	41 µm Polyester screen
OXYGENATOR MODULE	
MAXIMUM BLOOD FLOW RATE	6 l/min
STATIC PRIMING VOLUME (oxy module + heat exchanger average value)	284 ml
MEMBRANE SECTION	
- Surface area (approx. value)	1,4 m <sup>2</sup>
HEAT EXCHANGER SECTION	
- Material type	Polyurethane
- Surface area (approx. value)	0,4 m <sup>2</sup>
ARTERIAL FILTER SECTION	
- Material type	Polyester net
- Micron size	38 µ
- Surface area (approx. value)	68 cm <sup>2</sup>

### INSPIRE® 6 DUAL PH.I.S.I.O.

OXYGENATOR SYSTEM	
- Oxygenator system DOV @ max flow	402 ml
- Biocompatible coating	Phosphorylcoline (PHISIO)
RESERVOIR	
MAX. VOLUME CAPACITY (approx.)	4500 ml
MAX. OPERATING LEVEL (approx.)	4000 ml
- Non activated blood section	2700 ml
- Activated blood section	1300 ml
MIN. OPERATING LEVEL	
150 ml	
FILTRATION SECTIONS	
Venous reservoir section	
- Filtering media	41 µm polyester outer screen + 120 µm inner polyester net
Cardiotomy reservoir section	
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MAXIMUM BLOOD FLOW RATE	6 l/min
STATIC PRIMING VOLUME (oxy module + heat exchanger average value)	184 ml
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- Material type	Polyurethane
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STATIC PRIMING VOLUME (oxy module + heat exchanger average value)	284 ml
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HEAT EXCHANGER SECTION	
- Material type	Polyurethane
- Surface area (approx. value)	0,4 m <sup>2</sup>
ARTERIAL FILTER SECTION	
- Material type	Polyester net
- Micron size	38 µ
- Surface area (approx. value)	68 cm <sup>2</sup>

# ORDER GUIDE

INSPIRE® 6 PH.I.S.I.O.

ITEM #	DEVICE	DESCRIPTION	UNITS PER CASE
<b>INTEGRATED</b>			
050713	INSPIRE 6	INSPIRE 6 LPM PHISIO OXY MODULE WITH INTEGRATED PHISIO HARD SHELL VENOUS RESERVOIR	2
050715	INSPIRE 6F	INSPIRE 6 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER AND PHISIO HARD SHELL VENOUS RESERVOIR	2
050717	INSPIRE 6 DUAL	INSPIRE 6 LPM PHISIO OXY MODULE WITH INTEGRATED PHISIO DUAL CHAMBER HARD SHELL VENOUS RESERVOIR	2
050719	INSPIRE 6F DUAL	INSPIRE 6 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER AND PHISIO DUAL CHAMBER HARD SHELL VENOUS RESERVOIR	2

<b>OXY MODULES</b>			
050700	INSPIRE 6 M	INSPIRE 6 LPM PHISIO OXY MODULE	2
050702	INSPIRE 6F M	INSPIRE 6 LPM PHISIO OXY MODULE WITH INTEGRATED ARTERIAL FILTER	2

<b>RESERVOIR</b>			
050704	INSPIRE HVR	INSPIRE PHISIO HARD SHELL VENOUS RESERVOIR	2
050705	INSPIRE HVR DUAL	INSPIRE PHISIO DUAL HARD SHELL VENOUS RESERVOIR	2

<b>ACCESSORIES</b>			
050640	INSPIRE BKT	BRACKET FOR INSPIRE OXY MODULES AND INTEGRATED OXYGENATOR SYSTEMS	1
48-42-10	INSPIRE BKT FAST*	BRACKET FOR INSPIRE OXY MODULES AND INTEGRATED OXYGENATOR SYSTEMS WITH FAST CLAMP	1
050641	INSPIRE BKTH	BRACKET FOR INSPIRE HVR AND DUAL HVR RESERVOIRS	1
042229000	TEMPERATURE PROBES	TEMPERATURE PROBES	2

\* To be ordered as an accessory of LivaNova S5 and C5 HLMs



LivaNova's Green Leaf program

The Sorin Group Italia Quality  
System complies with:  
EN ISO 13485:2012/AC 2012

CE 0123 According to  
MDD 93/42/EEC amended by  
Directive 2007/47/EC

**LivaNova**  
Health innovation that matters

Manufactured by:  
**Sorin Group Italia Srl**  
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Please always refer to the Instructions For Use (IFU) manual provided with each product for detailed information, warnings, precautions and possible adverse side effects.

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